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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,920	02/10/2004	Qianjin Hu	Mergen-0010A	2124

7590

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,920	HU ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that "Since the decisions in *in re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631, F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the methods and products rely upon polynucleotides, polynucleotides, polypeptides and antibodies which differ in both structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.

2. With the election of Groups I-XVI Applicants are required to *further elect one gene or protein and its corresponding SEQ ID number*. This one gene or protein is considered reading on one Group or Invention. Applicants are put on notice *this is not a species election*.

Moreover, with the election of Group XVII Applicants are required to *further elect one protein* so that a search on its corresponding antibody can be conducted.

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3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method of breast cancer diagnosis comprising detecting over expression of a gene found in breast tissue, classified in class 435, subclass 6. Claims 1-3 will be examined with the instant Group to the extent nucleic acid is detected.
- II. Claims 1-4, 9, 10 and 42, drawn to a method of breast cancer diagnosis comprising detecting over expression of a protein found in breast tissue, classified in class 435, subclass 7.1. Claims 1-3 will be examined with the instant Group to the extent protein is detected.
- III. Claims 5-8, drawn to a method of breast cancer treatment comprising blocking over expression of a gene encoding a secreted or membrane-bound protein found in breast tissue, classified in class 536, subclass 24.5. Claims 5-8 will be examined with the instant Group to the extent nucleic acid is affected.
- IV. Claims 5-8 and 43, drawn to a method of breast cancer treatment comprising blocking an over expression a secreted or membrane-bound protein found in breast tissue with an antibody or binding portion thereof specific for elected protein, classified in class 436, subclass 64. Claims 5-8 will be examined with the instant Group to the extent protein is affected.
- V. Claims 11-14, drawn to a method of lung cancer diagnosis comprising detecting over expression of a gene found in lung tissue, classified in

class 436, subclass 501. Claims 11, 13 and 14 will be examined with the instant Group to the extent nucleic acid is detected.

- VI. Claims 11, 13, 14, 19, 20 and 45, drawn to a method of lung cancer diagnosis comprising detecting over expression of a protein found in lung tissue with an antibody or binding portion thereof, classified in class 436, subclass 387.1. Claims 11, 13 and 14 will be examined with the instant Group to the extent protein is detected.
- VII. Claims 15-18, drawn to a method of lung cancer treatment comprising blocking over expression of a gene encoding a secreted or membrane-bound protein found in lung tissue, classified in class 536, subclass 24.5. Claims 15-18 will be examined with the instant Group to the extent nucleic acid is affected.
- VIII. Claims 15-18 and 46, drawn to a method of lung cancer treatment comprising blocking an over expressed protein found in lung tissue, classified in class 436, subclass 64. Claims 15-18 will be examined with the instant Group to the extent protein is affected.
- IX. Claims 21-24, drawn to a method of colon cancer diagnosis comprising detecting over expression of a gene found in colon tissue, classified in class 436, subclass 501. Claims 21-24 will be examined with the instant Group to the extent nucleic acid is detected.
- X. Claims 21-24, 29, 30 and 48, drawn to a method of colon cancer diagnosis comprising detecting an over expressed protein with an antibody or

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binding portion of an antibody, classified in class 436, subclass 64.

Claims 21-24 will be examined with the instant Group to the extent protein is detected.

- XI. Claims 25-28, drawn to a method of colon cancer treatment comprising blocking over expression of a gene encoding a secreted or membrane-bound protein found in colon tissue, classified in class 424, subclass 9.1. Claims 25-28 will be examined with the instant Group to the extent nucleic acid is affected.
- XII. Claims 25-28 and 49, drawn to a method of colon cancer treatment comprising blocking an over expressed protein found in colon tissue, classified in class 436, subclass 174. Claims 25-28 will be examined with the instant Group to the extent protein is affected.
- XIII. Claims 31-33, drawn to a method of kidney cancer diagnosis comprising detecting over expression of a gene found in kidney tissue, classified in class 536, subclass 23.1. Claims 31 and 33 will be examined with the instant Group to the extent nucleic acid is detected.
- XIV. Claim 31, 33, 34, 39, 40 and 51, drawn to a method of kidney cancer diagnosis comprising detecting a over expressed protein with an antibody or binding portion of an antibody, classified in class 436, subclass 64. Claim 31 will be examined with the instant Group to the extent protein is detected.

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- XV. Claim 35-38, drawn to a method of kidney cancer treatment comprising blocking over expression of a gene encoding a secreted or membrane-bound protein found in kidney tissue, classified in class 424, subclass 9.1. Claims 35-38 will be examined with the instant Group to the extent nucleic acid is affected.
- XVI. Claims 35-38 and 52, drawn to a method of kidney cancer treatment comprising blocking an over expressed protein, classified in class 436, subclass 174. Claims 35-38 will be examined with the instant Group to the extent protein is affected.
- XVII. Claim 41, 44, 47 and 50, drawn to an antibody or binding portion of an antibody that specifically binds a protein found in breast tissue, classified in class 530, subclass 387.1.

4. The inventions are distinct, each from the other because of the following reasons:

The antibodies of Group XVII are a complex of glycoproteins capable of implementation in the methods of Groups II, IV, VI, VIII, X, XII, XIV and XVI. The methods of Groups I-XVI differ in the method objectives, method steps and parameters and in the reagents used. Each of the methods differ in the genes and their encoded protein products, which are distinct and separate secreted or membrane-bound proteins.

The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of

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different patentability issues.

Inventions I-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). Each method involves cancers from different organ systems, which present different and distinct histopathologies and are the result of different and distinct etiologic agents. Accordingly, these Groups are neither useable nor searchable together.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER


Alana M. Harris, Ph.D.
28 September 2006